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10/731,595	12/08/2003	Eugen Koren	11669.72USD1	5331

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER
1647	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,595	KOREN ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-48* is/are pending in the application.

4a) Of the above claim(s) *24,26,27,29,32,34,36,37 and 40-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,25,28,30,31,33,35,38,39 and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *23-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: IDS of 12/8/03 duplicative of that of 7/20/06.

DETAILED ACTION

Election/Restrictions

In response to the communication of 10/15/2007, applicants stated in their response of 10/24/2007 that:

"... Applicants elect the species of polypeptide modified by deletion, a species of thrombopoietin or cytokines, and further elect the species of TPO comprising amino acids 22-338 of SEQ ID NO: 13."

This corresponds to a deletion of residues 339-353 of human TPO, a deletion of the C-terminal 15 amino acids.

Applicants further state that: "Claims 23, 25-28, 30-39 and 43-48 read on the elected species."

The Examiner does not agree with applicants statement of claims corresponding to the elected species. For example, claim 26 calls for a modification of residues 312 to 332, which is not a deletion of 333-353, but in fact is a distinct species of the generic claim. Similarly, claim 27 calls for a modification in amino acids 318-332.

Accordingly, the Examiner finds that claims 26, 27, 32, 34, 36 and 37 do not correspond to the elected species, and are accordingly withdrawn from prosecution.

Claims 23, 25, 28, 30, 31, 33, 35, 38, 39 and 43-48 are under consideration, there being no allowable generic claim.

Claim Objections

Claim 24 is objected to because of the following informalities: there are inappropriate parentheses around "SEQ ID NO: 13" in the claim.

Appropriate correction is required

Claims 23, 28-31 and 33 are objected to because of the following informalities: In the status identifier, the word "original" is misspelled.

Claim 31 is objected to for being an improper dependent claim. Claim 30, from which it depends, is to a method of modifying a nucleic acid. Transforming a host cell with that nucleic acid does not relate to a method of modifying the nucleic acid.

Claim 44 is improperly dependent as a nucleic acid does not further limit the protein it encodes.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 12, 25 and 25 of U.S. Patent No. 6,673,580. Although the conflicting claims are not identical, they are not patentably distinct from each other because although there are minor differences in the wording of the claims (in fact rendering the instant claims indefinite), the claims are clearly substantially overlapping, and the instant claims fall within the scope of the patented claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 25, 28, 30, 31, 33, 35, 38, 39 and 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite because it claims a therapeutic polypeptide with reduced immunologic activity without specification of the peptide in question, or specifically where it is modified. The claim is drawn to a concept, rather than to a particular polypeptide or set of polypeptides. As such, the metes and bounds of the claim cannot be determined, and no meaningful search of the prior art can be performed. For the purpose of compact prosecution, the claim will be interpreted as reading upon the elected species in applying the prior art. See also the rejection of the same claim under 35 U.S.C. §112, first paragraph for lack of adequate written description, below.

The recitation of the claims of the term "modified" is taken to be a product by process limitation, indicating that there was a 'starting' polypeptide that has been altered to conform with the claimed limitations. As such, the limitation is only given weight to the extent that it dictates the structure of the claimed polypeptide. In those claims where no specific 'starting' polypeptide is designated, the limitation can be given no weight, and the claims are indefinite. For example, see claims 23, 24, 25, etc.

Further, the recitation "modification only in an immunodominant epitope" is indefinite, as it is not clear whether, if the modification is a deletion, that deletion may delete additional sequence, or is limited to the immunodominant epitope. With respect to the recitation that the modification is *only* in an immunodominant epitope it is noted that the specification breathes no life and meaning into this term. While terms are, in the absence of further definition to be given their ordinary meaning, it appears that applicants intend more than "within", as the claims also allow deletion of the entire epitope. Also, as it is well known in the art that epitopes may be discontinuous, the meaning of "within" an epitope is further indefinite as it is not clear whether the alteration is restricted only to those amino acids that comprise the epitope, or could involve intervening amino acids. Further, if, for example, residues 339-353 *are* an immunodominant

epitope, it is not clear how deletion of that entire sequence could be construed as a modification *in* that immunodominant epitope.

Claim 25 is indefinite for reciting "an" amino acid sequence; the indefinite article "an" implies that there are multiple sequences encompassed in the stated region; it cannot be determine whether the claim intends only the entire recited sequence, or portions thereof, and if so, which portions. Further, as the modified TPO does not need to retain any specified structure or function, the degree of modification, and therefore the metes and bounds of the claim, cannot be determined.

Claim 30 is an incomplete method claim. The identification of the immunodominant epitope is essential to the invention. However, no method steps are recited to accomplish such. The claim is also indefinite because part (c) says that a "substantial therapeutic activity" must be maintained, however there is no corresponding limitation earlier in the claim. Finally, the recitation that the change "reduces an immune response" is a relative limitation, and would depend on the nature of the peptide, the species, genotype and health of the individual to whom it is administered, such that the metes and bounds of the claim cannot be determined. Claim 35 is similarly indefinite.

Claim 35 is indefinite for reciting "native" thrombopoietin. The term could indicate having a "native" sequence, or alternatively that the protein is not denatured. Further, if applicants intend the former interpretation, as not all "native" TPO sequences have been discovered or characterized, the person of ordinary skill in the art would not be able to determine whether or not a given sequence was "native".

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 28, 33, 35, 38, and 43-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The rejected claims fall into two groups; claims 23, 28 and 33 are generic, in that they specify no particular protein, whereas claims 35, 38 and 43-48 are drawn specifically to thrombopoietin.

With respect to the former, it is acknowledged that applicants hold a patent to a *method* of making such variants. However, as stated above, claim 23 is indefinite because it claims a therapeutic polypeptide with reduced immunologic activity without specification of the peptide in question, or specifically where it is modified. The claim is drawn to a concept, rather than to a particular polypeptide or set of polypeptides. As such, the metes and bounds of the claim cannot be determined, and no meaningful search of the prior art can be performed. In addition to being indefinite, the claim lacks adequate written description; there is no way the Examiner can envision what species would or would not fall within the metes and bounds of the claim. The concept of making such variants is not a *description* of the variants so found. In this case, there can be no conception prior to reduction to practice. Accordingly, the description fails to support the claims.

With respect to claims 35, 38 and 43-48, while there is specific description of the elected species, the description is not commensurate in scope with the claims.

The specification states at paragraph [0069] that "An immunodominant epitope of human thrombopoietin includes amino acids 318 to 332..." Noticeably, it does *not* say that the epitope *consists* of those residues (contributing to the indefiniteness of the claim), nor does it say that that is the *only* immunodominant epitope. In fact, the opposite appears to be true, as the elected species does not affect that region. Accordingly, while there is description of species that are mutated within that region, or that comprise deletions that delete that entire region, or the elected species, there is no written description of any other species within the claims. As the breadth of the claims is not limited to what is described, and as there cannot be conception prior to the identification of the immunodominant epitope and determination of how it can be altered without destroying protein activity, the written description is not commensurate in scope with the claims.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides or proteins, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only thrombopoietin having alterations in the sequence at positions 318-332 (none of which would be expected to alter the biological activity of the protein) , but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 23, 28, 30, 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/10755 (Lovborg et al.), cited by applicants.

Lovborg et al. disclose a method of mapping immunodominant epitopes of desired proteins, and then producing less immunogenic variants of such proteins by recombinant DNA methods; see abstract and claims, especially claims 1, 5, 6, 18 and 19. Preferred proteins to be mutated include "medicinal proteins, e.g. hormones, e.g. insulin, HCG, or growth hormone, or medicinal enzymes...", and "interleukins, or interferons, are of special interest." See page 5. The epitope mapping is performed using antibodies, see pages 6-7. They state that the epitopes in the protein are changed by genetic engineering or chemical modification through 'well established techniques' see page 6. Exemplified species were made via substitution or deletion of residues, see page 10. Human proteins are preferred species, see page 2. Since Lovborg teaches medicinal proteins, pharmaceutical compositions are clearly envisioned. Accordingly, the claims are anticipated by Lovborg.

Claims 23, 28, 33, 35, 38, and 43-48 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5641655 (Foster et al.).

Foster et al. teach truncated variants of human TPO:

Brief Summary Text - BSTX (6):

Analysis of amino acid sequences indicates that the mature mouse TPO extends from amino acid residue 45 (Ser) to residue 379 Thr) [corresponding to residues 22-353 of applicant's sequence of SEQ ID NO: 2. The predicted amino terminus of the human protein corresponds precisely to the demonstrated mature amino terminus for recombinant murine TPO (Lok et al., ibid.), i.e. it is at Ser (22) of SEQ ID NO:4, with the protein extending to amino acid residue 353 of SEQ ID NO:4. TPO is subject to proteolysis and has been isolated in heterogeneous or degraded form (de Sauvage et al., Nature 369:533-538, 1994; Bartley et al., Cell 77:1117-1124, 1994). Molecular species as small as 25 kD have been found to be active in vitro (Bartley et al., ibid), and recombinant human TPO polypeptides of 153 (de Sauvage et al., ibid) and 174 amino acids (Bartley et al., ibid) have been reported as being active in vitro, as has the product of expression of the full-length human cDNA, which encodes a primary translation product of 353 amino acids (Bartley et al., ibid).

At paragraphs DETX(33) and (35), Foster teaches treatment of thrombocytopenia, and pharmaceutical compositions, respectively. In view of the rejections under 35 U.S.C. §112, above, a TPO variant having at least residues 339-353 deleted would anticipate the elected species. Accordingly, the claims are anticipated by Foster et al.

Claims 23, 25, 28, 33, 35, 38 and 43-48 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6608183 (Cox et al.).

Cox teaches modifiction of proteins to introduce cysteine residues in non-essential regions of the proteins. The cysteines can then be used for coupling to polyethylene glycol or other moieties. With specific reference to TPO, Cox teaches at paragraph DETX (117)that Preferred sites for introduction of cysteine residues include T312, T314, S315, N319, T320, S321, T323, S325, Q326, N327, L328, S329, Q330, E331 and G332. Variants in which cysteine residues are introduced proximal to the first amino acid of the mature protein, i.e., proximal to S1, or distal to the final amino acid in the mature protein, i.e., distal to G332 are provided. The cysteine-added variants are also provided in the context of the natural human protein or a variant protein that is truncated between amino acids 147 and the C-terminus of the natural protein, G332. Note that Cox's numbering differs from applicants in that residue 332 of Cox corresponds to residue 353, or the final amino acid of the mature protein. Variants in which cysteine residues are added distal to the final amino acid of a TPO protein that is truncated between amino acids 147 and 332 also are provided.

of Bartley et al., U.S. Patent Number 5,795,569, cited by applicants, and in the case of claim 7 further in view of Garrity et al., U.S. Patent Number 5,585,250.

This additional rejection is made to address the elected species, thrombopoietin. The teachings and findings of obviousness with respect to growth hormones and cytokines generically, are given above. Bartley et al. Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to apply the methods found obvious above to thrombopoietin or MGDF, as taught by Bartley et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al., U.S. Patent No. 6,608,183.

Claim 39 contains the limitation that the modification to TPO *consists* of a deletion of residues 339-353.

The teachings of Cox et al. are summarized above. Of specific interest is the teaching that the cysteine-added variants are also provided in the context of the natural human protein or a variant protein that is truncated between amino acids 147 and the C-terminus of the natural protein, G332. Note that Cox's numbering differs from applicants in that residue 332 of Cox corresponds to residue 353, or the final amino acid of the mature protein. Given the limited number of places for truncation, any one of the specific deletions encompassed is obvious. Accordingly, the claimed species is *prima facie* obvious.

The Examiner's position is supported by the recent finding by the Supreme Court in *KSR v. Teleflex, Inc.* (82 USPQ 2d 1385, 4/30/2007), which held that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." (See 82 USPQ2d at 1397.) In this instance, there are a limited number of deletions that would be expected to retain biological activity, i.e. known options, each of which would have been expected to retain therapeutic activity.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Garrity et al. U.S. Patent Number 5,585,250 teach "immunodampening", or the 'hiding' of epitopes, by adding N glycosylation sites to a desired protein, see columns 4 and 6.

Therefore, adding glycosylation as taught by Cox et al. would be expected to reduce the immune response of an organism to the resulting protein.

Bartley et al., U.S. Patent Number 5,795,569, cited by applicants teach that it is desirable to decrease the immunogenicity of TPO, referred to therein as MGDF. See column 5 lines 21.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Dr. Manjunath Rao, at telephone number 571-272-0939.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lorraine Spector/ , Ph.D.
Primary Examiner
Art Unit 1647

[LS1]